(12) UK Patent Application (19) GB (11) 2 364 643 (13) A

(43) Date of A Publication 06.02.2002

(21) Application No 0017268.4

(22) Date of Filing 13.07.2000

(51) INT CL[7]
A61F 2/44

(52) UK CL (Edition T)
A5R RAS

(56) Documents Cited
GB 2338652 A
WO 96/17564 A1
US 5458641 A
EP 0179695 A1
WO 95/20370 A1
US 4892545 A

(58) Field of Search
UK CL (Edition S) A5R RAS
INT CL[7] A61F 2/44

(71) Applicant(s)
Biomet Merck Limited
(Incorporated in the United Kingdom)
Waterton Industrial Estate, Bridgend, CF31 3XA,
United Kingdom

(72) Inventor(s)
James William Truscott
J Lehovsky

(74) Agent and/or Address for Service
Haseltine Lake & Co
Imperial House, 15-19 Kingsway, LONDON,
WC2B 6UD, United Kingdom

(54) Abstract Title
Vertebral body replacement

(57) A spinal prosthesis (1) comprises a hollow strut (2) terminated by a pair of end caps (110) which are adapted to engage respective vertebrae. A fixing element (150) is connected to each end cap (110) and is adapted for securement to a side surface of one of the said vertebrae. Each fixing element (150) may be waisted in a region adjoining the end cap (110). Preferably, each fixing element (150) has a pair of flexible arms (152) that project outwardly in substantially laterally opposing directions and which may be inclined to the coronal plane to facilitate implantation. The arms (152) may subsequently be bent such to enclose an adjacent vertebral body. Through holes (153) may be provided for fixing screws to permit secure attachment to the spine using rods or bone screws.

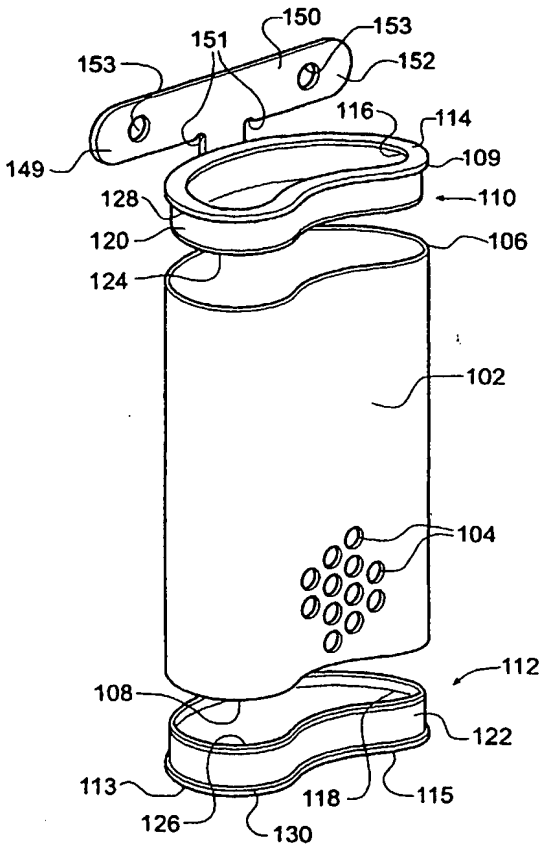

Fig. 1

GB 2 364 643 A

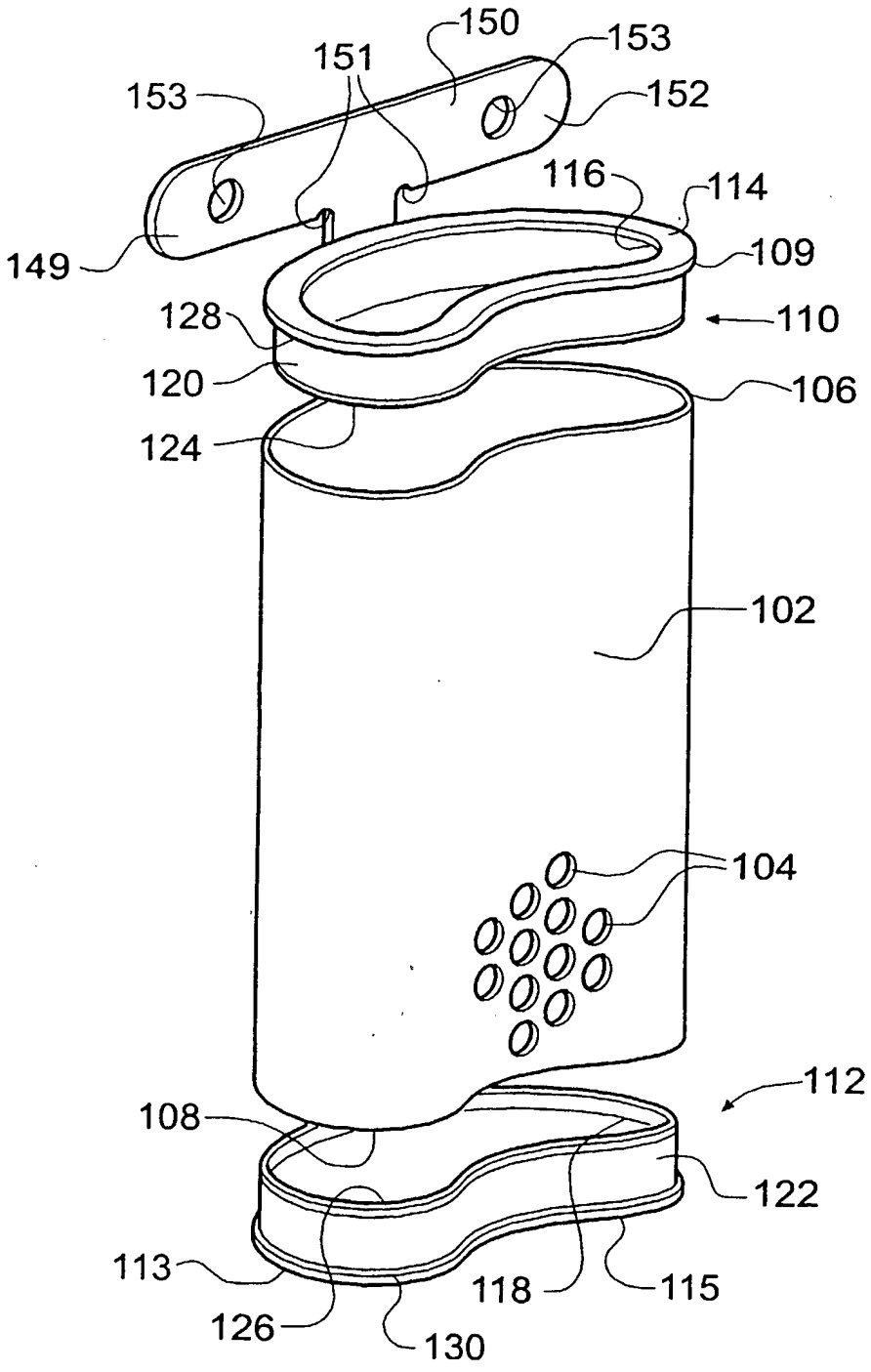
150
153
151
153
152
116
114
149
109
128
110
120
106
124
102
104
112
108
122
113
118
115
126
130

Fig. 1

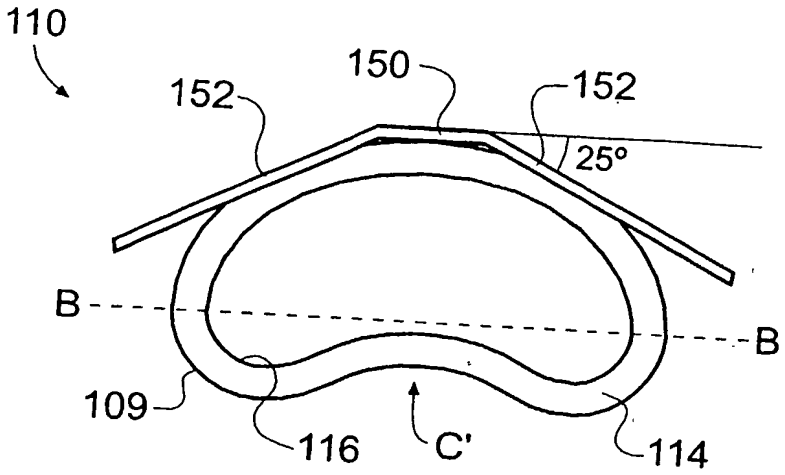

Fig. 2

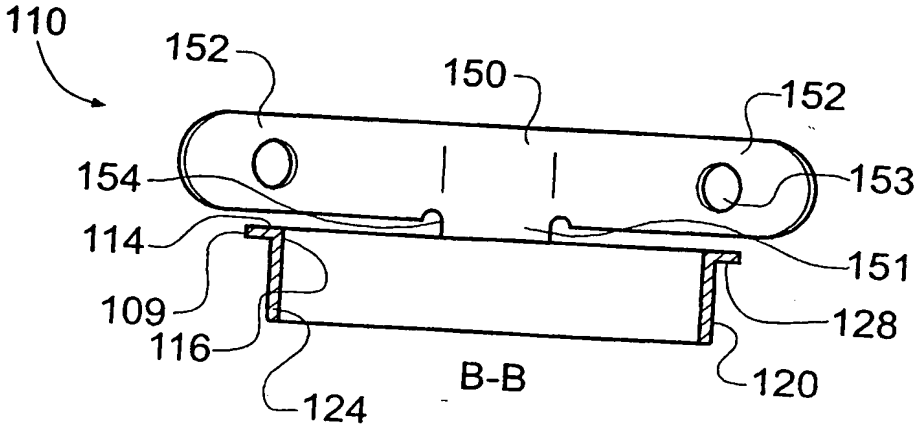

Fig. 3

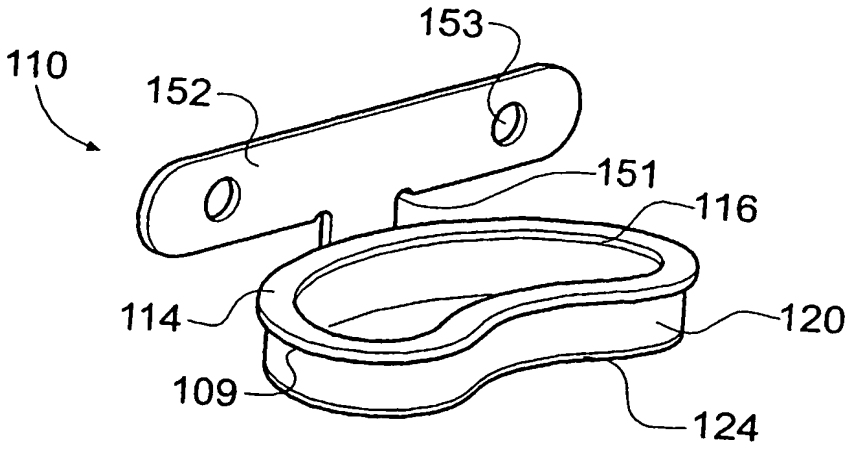

Fig. 4

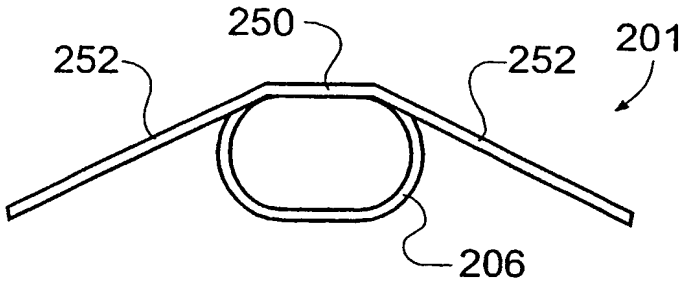

Fig. 5

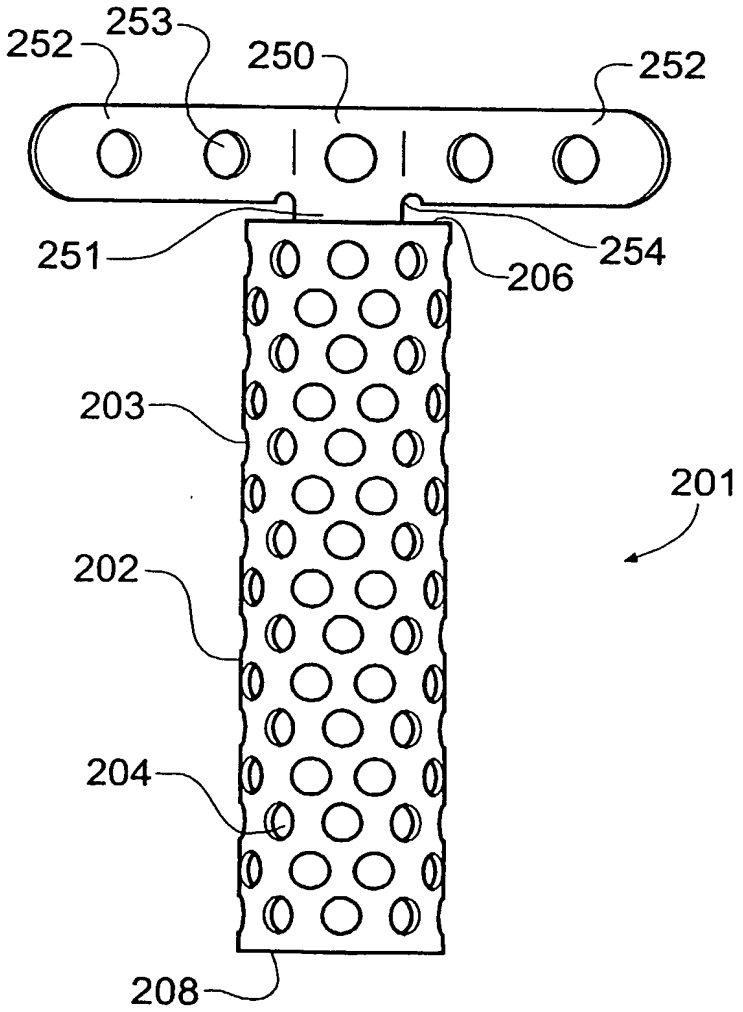

Fig. 6

VERTEBRAL BODY REPLACEMENT

This invention relates to a spinal prosthesis for supporting or replacing all or part of one or more vertebral bodies.

BACKGROUND TO THE INVENTION

The treatment of spinal fractures and tumours often requires the implantation of a prosthesis capable of substituting for the affected vertebra.

In the absence of any commercially available implants, spinal surgeons have used bone cement as a crude spacer. PMMA cement has sufficient compressive strength to replace bone for the space of one vertebra. If more than two vertebrae are involved, then the cement must be reinforced with metal rods which function as compression struts.

Although PMMA cement was widely used in this application, it does have disadvantages. More specifically, it is difficult to prepare a cement bridge which is dimensionally accurately enough to restore correct spinal alignment and to install easily. Intraoperatively, soft tissues have a tendency to fold or curl over the edge of the anterior rim and enter the intervertebral space, thus causing the anterior rim to be insufficiently supported. This can lead to displacement of the cement bridge. There is also a risk of infection with cement struts. The infection risk is increased partly because of the longevity of the surgery, and because of biological reaction with cements which contain antibiotics. To address this, cements have been developed specifically for this type of procedure, to reduce the incidents of infection. The cement in these procedures is mixed to a dense paste and is fitted into the spine. This then cures in vivo. As it cures it generates heat, risking thermal damage to the neural pathways. A 4 to 12°C rise in tissue temperature at the dural sac has been measured

in experiments in cadavers. Although this technique is still in use today, it is confined to end stage patients.

Alternative systems have also been proposed and current commercially available instrumentation includes, among other systems, bracing devices and sophisticating jacking devices. These jacking devices all follow the same basic pattern, although to different levels of sophistication. Each uses opposite handed thread arrangements to adjust the implant height and can be locked off once the correct height and position is achieved. They only differ in the means by which they are fixed to the vertebrae, and in the degree of anatomic accuracy. These existing systems have been partially successful, but there have been reports of subsidence or anterior translation with attendant problems of hyperkyphosis and pain.

Our existing patent application GB 2 338 652 A discloses a prosthesis comprising a hollow strut terminated by a pair of end caps which are adapted to engage respective vertebrae. Each end cap is provided with a flange closely received within and supporting a respective end of the strut.

The end caps may be provided with spikes to increase the engagement of the end caps with the adjacent vertebra. For most patients, this has provided sufficient anchorage of the end caps, but in some patients, additional anchorage is desirable.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention there is provided a prosthesis for replacing at least part of a spine comprising;

a strut which is adapted to space apart and support end surfaces of respective vertebrae;

an end cap which is removably connectable to an end of the strut; and

a fixing element which is connected to the end cap and is adapted for securement to a side surface of one of the said vertebrae.

Such an arrangement is advantageous in providing additional anchorage of the prosthesis.

Preferably, each fixing element has a pair of semi-rigid arms that project outwardly in substantially laterally opposing directions and which may be inclined to the coronal plane to facilitate implantation. The arms of the fixing element may initially be inclined at no more than 25°. The fixing element may be provided with at least one through hole, to enable secure attachment to the spine using rods or bone screws. The or each through hole may be elongated.

The fixing element may be waisted in a region adjoining the end cap.

In a preferred embodiment, at least a part of the end cap is closely received within and supports the said end of the strut. Preferably, the edge of the end cap directed towards the strut is chamfered, which assists alignment of the end cap with the hollow strut and facilitates assembly. To ensure long term stability and resistance to subsidence, the end cap is preferably substantially kidney shaped so that it approximates to the anatomic shape of the hard outer cortex of the vertebral bodies of the vertebrae.

Preferably, in a region away from the periphery, the end wall is provided with a kidney shaped recess.

Preferably, the recess comprises a through hole which provides access to the interior of the strut.

Preferably, the end cap is provided with a shoulder which is adapted to cover the end of the strut and to prevent the end of the strut damaging the surrounding soft tissue.

Preferably a porous titanium plasma coating is applied to the end cap to enhance bone fixation and to

resist anterior translation and rotation of the prosthesis by biting into the subcondral bone. When the prosthesis is implanted and under a compression load, there will be intimate contact between the porous coating and the bone. This helps enhance primary stability and encourages osseointegration.

According to a second aspect of the present invention there is provided a prosthesis for replacing at least part of a spine comprising a strut having at one end a fixing element which is adapted to engage a side surface of a vertebra, the fixing element being permanently connected with the strut.

Preferably, the fixing element is integrally formed with the strut. This makes the surgical procedure less complex and helps facilitate assembly.

Preferably, each fixing element has a pair of flexible arms which project outwardly in substantially laterally opposing directions and which may be inclined to the coronal plane to facilitate implantation. The arms of the fixing element may initially be inclined at no more than 25°. The fixing element may be provided with at least one through hole, to enable secure attachment to the spine using rods or bone screws. The or each through hole may be elongated.

The fixing element may be waisted in a region adjoining the strut. Preferably, the prosthesis further comprises a second end cap which is removably connectable to the other end of the strut.

The strut may be terminated at the other end by a second fixing element which is adapted to engage a side surface of a vertebra, the second fixing element being permanently connected with the strut and adapted for securement with a bone.

To ensure long term stability and resistance to subsidence, the strut is preferably substantially kidney shaped in cross section so that the prosthesis

as a whole has a posterior concavity which, when implanted, accommodates the spinal cord.

Preferably, the strut comprises a tube made of titanium. The tube may be heat treated and seam welded or extruded. Preferably, the tube has a 0.9 mm thick wall.

The strut may be provided with a plurality of through holes. Preferably, the hole pattern is configured to enable trimming to length to suit individual patient need, such as to allow for a degree of lordoses and kyphoses.

Preferably, the prosthesis is stabilised by rods and bone screws. For example, 5mm diameter transvertebral rods and 6.5mm diameter bone screws may be used. These screws and rods are preferably based on a top loading collet locking system such as the Webb-Morley system. The screws and rods are preferably used anteriorly to bridge the prosthesis and may also be used posteriorly to further strengthen the total assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention and to show how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Figure 1 is a perspective view of a prosthesis in accordance with the present invention;

Figure 2 is a plan view of an end cap having a fixing plate in accordance with a first aspect of the present invention;

Figure 3 is a partial cross sectional side view of the end cap of Figure 2 taken along the line B-B;

Figure 4 is a perspective view of the end cap viewed in Figures 2 and 3 with the arms of the fixing plate fully extended;

Figure 5 is a plan view of a prosthesis having a

permanently connected fixing element in accordance with a second aspect of the present invention;

Figure 6 is a side view of the prosthesis as viewed in Figure 5.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Figure 1 shows a prosthesis for use in the treatment of spinal tumours and fractures. The prosthesis 101 comprises a strut 102 formed from a heat treated titanium tube in which are formed a plurality of perforations 104. The ends 106, 108 of the strut 102 are terminated by respective end caps 110, 112 which are a push fit into the ends 106, 108.

The strut 102 and end caps 110, 112 have a substantially kidney shaped cross-section and the internal diameter of the strut is sized such that the end caps 110, 112 are closely received within the ends 106, 108 of the strut 102.

Each end cap 110, 112 comprises an end wall 109, 113 having a bone engaging surface 114, 115 which is disposed in a plane substantially perpendicular to the longitudinal axis AA of the strut 102. A kidney shaped central opening 116, 118 is formed in each end wall 109, 113 and limits the bone engaging surface 114, 115 to the periphery of the end wall 109, 113 of the respective end cap 110, 112. A continuous flange 120, 122 projects at right angles from the end wall 109, 113 and forms the main body of each end cap 110, 112. The free end 124, 126 of each flange 120, 122 is chamfered to ease insertion into the strut 102.

The end wall 109, 113 of each end cap 110, 112 extends radially outwardly beyond the respective flanges 120, 122 to form shoulders 128, 130. A fixing element 150 projects at right angles from an edge of the end wall 109 and is provided with two arms 152 which extend in laterally opposing directions. The

arms 149, 152 are flexible and whilst initially inclined at no more than 25 degrees to the coronal plane (as viewed when implanted in a patient) to facilitate implantation in a patient, they may be bent subsequently, so as to enclose an adjacent vertebral body. The fixing element 150 and arms 149, 152 are provided with through holes 153 to permit secure attachment to the spine using rods or bone screws.

The fixing element 150 is joined to the end cap 110 by means of a neck or waist 151 projecting at right angles from the end wall 109. The waist 151 is provided with semicircular cut-outs or recesses 154 on both lateral sides, to reduce mechanical stress.

In a vertebral body replacement operation, the damaged or tumorous vertebral body (not shown) is cut away and the strut 102 is trimmed, so that the prosthesis as a whole will be of the correct length to replace the excised vertebral body. The end caps 110, 112 are then pushed into the open ends of the strut until the respective shoulder 128, 130 abuts the respective end 106, 108 of the strut 102. As will be appreciated, the shoulders 128, 130 cover the otherwise exposed ends 106, 108 of the strut 102, which may be rough or jagged, following the trimming operation.

Following assembly, the prosthesis is inserted into the space left by the excised vertebral body, such that the spinal cord is accommodated by the posterior concavity C generated by the kidney shaping of the end caps 110, 112 and the strut 102 and such that the bone engaging surfaces 114 engage the end plates of the adjacent vertebral bodies. As discussed above, the vertebral body end plates are approximately kidney shaped and have a soft cancellous centre and hard outer cortex of bone capable of withstanding compression loading. In the implanted condition, the kidney shaped bone engaging surfaces 114 of the end caps 110, 112 are

aligned with the hard outer cortex of bone of the vertebral body end plates and the openings 116, 118 are aligned with the soft cancellous centre of the end plates, so that the compressive loading on the spine is carried directly from the hardest part of the end plates into the bone engaging surfaces 114, 115 of the respective end cap 110, 112.

Whilst end cap 110 is shown in Figures 2-4 as being generally kidney shaped, it is appreciated that end cap 110 may be formed into circular, oval, crescent or any complex polynomial shape in accordance with the present disclosure. For example, where the end cap is to be fitted to cervical vertebrae, it is preferably substantially oval in cross-section.

Prior to insertion of the prosthesis, bone graft or bone cement may be packed inside the interior of the strut 102 through the openings 116, 118 in the end caps 110, 112. If the interior of the strut 102 and end caps 110, 112 is completely filled with bone cement, the adjacent vertebral bodies will impinge directly on the bone cement which fills the openings 116, 118, so that there will be direct contact not only between the bone engaging surfaces 114 and the hard outer cortex of the end plate but also between the bone cement and the soft cancellous centre of the end plates. Any excess bone cement will be squeezed to the outside of the prosthesis and can be removed, so that once the bone cement has set, the prosthesis is an exact fit between the adjacent vertebral bodies and is therefore resistant to dislocation. Furthermore, as the load is transferred into the strongest parts of the adjacent vertebral bodies, post-operatively, the patient's spine will be able to withstand substantially the same compressive loads that it could withstand pre trauma or disease.

Once the prosthesis is in place, it is anchored

firmly to an adjacent vertebra by means of bone screws, nails or other fixings which are driven through the openings 153 in the fixing element 150 into the side of the said vertebra.

In order to improve the stability of the prosthesis, the bone engaging surfaces 114, 115 of the end caps and the bone engaging surfaces of the or each fixing element are provided with a porous titanium plasma coating which roughens the bone engaging surfaces and causes them to bite into the subcondral bone. The titanium porous coating acts as a host media for bony ingrowth, so long term fixation is also improved. It will be appreciated that a variety of surface coatings or textures can be applied to promote bone growth or anti-skid features to prevent movement against bone increasing stability.

Figures 5 and 6 illustrate a second embodiment of prosthesis according to the present invention. Prosthesis 201 comprises a strut 202 having a plurality of perforations 204 which substantially correspond to those of strut 2. Fixing elements 250 project axially from one or both ends 206, 208 of the strut 202. Each fixing element 250 is permanently connected to strut 202 via a neck or waist 251. The corners of the intersection at which waist 251 and the body portion 202 of the strut meet are recessed with a large radius, to ensure that mechanical stress around waist 351 is minimised.

As for the previous embodiment, during a vertebral body replacement operation, the diseased or damaged tissue is removed and the strut is put in its place after being filled with bone cement. Bone screws, nails or other fixings are then driven through the openings 253 into the side of an adjacent vertebra to stabilise the prosthesis.

By providing a single prosthesis 201 which does

not require separate end caps to be fitted, the surgical procedure is made less complex and the cost is reduced.

A single prosthesis in accordance with the present invention may be used to replace or support all or part of more than one vertebral body.

CLAIMS

1. A prosthesis for replacing at least part of a spine comprising;
a strut which is adapted to space apart and support end surfaces of respective vertebrae;
an end cap which is removably connectable to an end of the strut; and
a fixing element which is connected to the end cap and is adapted for securement to a side surface of one of the said vertebrae.

2. A prosthesis as claimed in claim 1, in which at least a part of the end cap is closely received within and supports the said end of the strut.

3. A prosthesis as claimed in claims 1 or 2, in which the fixing element is waisted in a region adjoining the end cap.

4. A prosthesis as claimed in any preceding claim, in which the edge of the end cap directed towards the strut is chamfered.

5. A prosthesis as claimed in any preceding claim, in which the end cap is substantially kidney shaped in a plane substantially perpendicular to the longitudinal axis of the strut.

6. A prosthesis as claimed in any preceding claim, in which the end cap has an end wall which is adapted to engage a respective vertebra, a periphery of the end wall extending radially further from the strut than the remainder of the end wall.

7. A prosthesis as claimed in claim 6, in which in a

region away from the periphery, the end wall is provided with a kidney shaped recess.

8. A prosthesis as claimed in claim 7, in which the recess comprises a through hole which provides access to the interior of the strut.

9. A prosthesis as claimed in any preceding claim, in which the end cap is provided with a shoulder which is adapted to cover the end of the strut.

10. A prosthesis as claimed in any preceding claim, in which the end cap is a press fit into the strut.

11. A prosthesis as claimed in any preceding claim, further comprising a second end cap which is removably connectable to the other end of the strut.

12. A prosthesis for replacing at least part of a spine comprising a strut having at one end a fixing element which is adapted to engage a side surface of a vertebra, the fixing element being permanently connected with the strut.

13. A prosthesis as claimed in claim 12, in which the fixing element is integrally formed with the strut.

14. A prosthesis as claimed in claims 12 or 13, in which the fixing element is waisted in a region adjoining the strut.

15. A prosthesis as claimed in any one of the preceding claims, in which when the prosthesis is implanted in a patient, the fixing element is

disposed substantially in the coronal plane of the patient.

16. A prosthesis as claimed in any one of the preceding claims, in which a porous titanium plasma coating is applied to at least part of the prosthesis.

17. A prosthesis as claimed in any one of claims 12-16, in which the strut is further terminated at the other end by a second fixing element which is adapted to engage a side surface of a vertebra, the second fixing element being permanently connected with the strut and adapted for securement with a bone.

18. A prosthesis as claimed in any one of the preceding claims, in which the fixing element has a pair of arms that project outwardly in substantially laterally opposing directions.

19. A prosthesis as claimed in claim 18, in which at least a portion of the arms of the fixing element are flexible.

20. A prosthesis as claimed in claim 19, in which the arms of the fixing element are initially inclined at no more than 25° to the coronal plane.

21. A prosthesis as claimed in any one of the preceding claims, in which the fixing element is provided with at least one through hole.

22. A prosthesis as claimed in claim 21, in which the or each through hole is elongated.

23. A prosthesis as claimed in any one of the preceding claims, in which the strut is substantially kidney shaped in cross-section.

24. A prosthesis as claimed in any one of the preceding claims, in which the strut comprises a heat treated titanium tube.

25. A prosthesis as claimed in any one of the preceding claims, in which the strut is provided with a plurality of through holes.

26. A prosthesis as claimed in claim 25, in which the through holes are aligned in rows substantially perpendicular to the longitudinal axis of the strut.

27. A prosthesis as claimed in claims 25 or 26, in which the through holes are elongated.

28. A prosthesis substantially as described herein, with reference to, and as shown in, one or more of the accompanying drawings.

Application No: GB 0017268.4
Claims searched: 1-11 and 15-28 (in part)
Examiner: Dr Jeremy Kaye
Date of search: 26 January 2001

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R (RAS)

Int Cl (Ed.7): A61F 2/44

Other:

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2338652 A	(BIOMET) whole document.	1, 2, 11, 21
A	EP 0179695 A1	(KEHR) p.4 ll.10-22; p.7 ll.1-18; p.8 ll.17-20.	1, 15, 18, 21, 22
X, Y	WO 96/17564 A1	(SOFAMOR DANEK) p.6 ll.1-26; p.7 l.9 - p.8 l.27; p.10 l.13 - p.12 l.36; Fig.3.	X: 1, 2, 11, 15, 21, 25 Y: 1, 2, 11, 21
A	WO 95/20370 A1	(IMPLEX) p.6 l.17 - p.7 l.6; p.9 ll.1-13; p.14 ll.3-10; p.16 l.1 - p.17 l.17; Fig.5.	1, 15, 21
X, Y	US 5458641	(JIMENEZ) col.1 l.36 - col.2 l.12; col.2 l.51 - col.3 l.12; col.3 l.61 - col.4 l.32; Fig.1.	X: 1, 2, 6, 11, 15, 21 Y: 1, 2, 11, 21
A	US 4892545	(DAY ET AL.) Fig 1; col.3 ll.34-43.	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.